NOV - 4 1997
K964397

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Thermolabile Technologies Corp. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." TTC chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	**Therapik®**
Owner/Operator:	Thermolabile Technologies Corp. 5407 Eglinton Avenue West, Suite 200 Etobicoke, Ontario, Canada M9C 5K6
Manufacturing Site:	**Not yet determined**
Device Generic Name:	**Therapeutic heating device**
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 890.5500).
Predicate Devices:	**Health Team Model 501500 Infrared Heater** **(Manufacturer unknown)** **Model HT510-500 Infrared Heater** **Distributed by:** **Graham Field, Inc.** **400 Rabro Drive, East** **Hauppauge, NY 11788** **Model NH-202 Infrared Heat Lamp** **Distributed by:** **National Health Care Equipment Inc.** **144 East Kingsbridge Road** **Mount Vernon, NY 10550** **Body Relaxer Infrared Heater and Massager** **(Manufacturer unknown)** **Distributed through the adaptAbility catalog (800-266-8856)** **Li's Itch Stopper** **Hontech Foundation for Medical Technology** **402 Rindge Avenue, 17H** **Cambridge, MA 02140** **K963824**

Product Description:

The Therapik is a small, portable, hand-held, battery-powered device equipped with a carrying wrist strap. It measures approximately 3cm x 3cm x 10cm and weighs less than 4 ounces, including the 9 volt battery. The heat is initiated by use of a simple, non-locking, finger-or thumb-activated on/off switch. Heat is produced by pressing the switch. The Therapik device delivers 50 - 60°C heat directly on the user's skin. The user is instructed to apply the device for as long as the heat is comfortable on the skin (approximately 20 - 30 seconds).

Indications for Use:

The proposed Therapik device will be indicated for the temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes by increasing localized blood flow.

Safety and Performance:

Comparative performance testing was performed on the proposed Therapik device and the predicate National Health Care NH-202 device to establish the comparability of the operating Time/Temperature Profile and the Maximum Operating Temperature of the two devices. The operating characteristics, recommended use time, operating temperature and labeling of the proposed Therapik were also compared to corresponding characteristics of the currently marketed Li's Itch Stopper.

Clinical safety and effectiveness data from clinical trials on the Therapik device conducted in Venezuela (35 subjects) and France, Italy and Reunion (34 subjects) was presented. The 69 total users applied the Therapik to a variety of stings and bites from venomous and non-venomous insects and sea creatures such as bees, wasps, hornets, ants, fleas, ticks, nettles, weaver fish, scorpion fish and jellyfish. Each user was asked to rate the effectiveness of the device in relieving pain and inflammation from the injuries using a subjective rating of 1 (total/complete disappearance of the pain), 2 (distinct alleviation of pain), 3 (slight alleviation of pain) or 4 (not effective). Device ratings were as follows:

Total/complete disappearance of pain = 61/69 users
Distinct alleviation of pain = 7/69 users
Slight alleviation of pain = 1/69 users
Not effective = none

No serious side effects related to the use of the Therapik were reported.

A fifty-subject study on a similar device (Body-Pic) marketed in Canada was also referenced; here, fifty users reported the device to be effective when used to treat the stings and bites of bees, horseflies, wasps, ticks, hornets, sand fleas, ants, and Brulots (mosquitoes).

(Note: Although the clinical data included a variety of insect and sea creature injuries, Therapik is not indicated at this time for the treatment of stings/bites of animals and insects other than bees and wasps).

Conclusion:

Based on the indications for use, technological characteristics, and clinical testing, the Therapik device has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Pamela Papineau
Delphi Medical Device Consulting
Representing Thermolabile Technologies Corporation
50 Brewster Street
Pawtucket, Rhode Island 02860

NOV - 4 1997

Re: K964397
Trade Name: Therapik®
Regulatory Class: II
Product Code: ILY
Dated: August 19, 1997
Received: August 21, 1997

Dear Ms. Papineau:

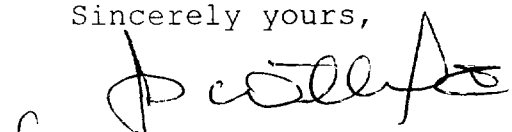
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K964397/A2

Device Name: Therapik®

Indications for Use:

The Therapik is indicated for use to provide temporary relief of the pain and itching resulting from insect stings and bites such as bees, wasps and mosquitoes by increasing localized blood flow.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K964397

Prescription Use _____ OR Over-the -Counter Use X
(Per 21 CFR 801.109)